DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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MAR - 1 2000

WARNING LETTER

VIA FEDERAL EXPRESS
VIA FACSIMILE

Mr. Robert L. Sands
Chief Executive Officer
Sands Hyperbaric Systems (SHS)
462 North Linden Drive
Suite 440
Beverly Hills, California 90212

Re: Sands Series III Clinical
Hyperbaric Chamber, K972908

Dear Mr. Sands:

The Food and Drug Administration (FDA) has reviewed your web site for the Sands Series III Clinical Hyperbaric Chamber (Sands Hyperbaric Chamber) at the Internet address: http://www.hyperbarics.net. The Sands Hyperbaric Chamber is manufactured by Sands Hyperbaric Systems (Sands) and is a device as defined within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The FDA has cleared the Sands Series III Clinical Hyperbaric Chamber under section 510(k) of the Act for the following 13 intended uses:

-Air or Gas Embolism;
-Carbon Monoxide Poisoning and Smoke Inhalation; Carbon Monoxide Poisoning Complicated by Cyanide Poisoning;
-Clostridial Myositis and Myonecrosis (Gas Gangrene);
-Crush Injury, Compartment Syndrome, and other Acute Traumatic Ischemias;
-Decompression Sickness;
-Enhancement of Healing in Selected Problem Wounds;
-Exceptional Blood Loss (Anemia);
-Intracranial Abscess, Actinomycosis;
-Necrotizing Soft Tissue Infections;
-Osteomyelitis (Refractory);
-Delayed Radiation Injury (Soft Tissue and Bony Necrosis);
-Skin Grafts and Flaps (Compromised);
-Thermal Burns.

Our review of the Sands web site indicates that Sands has provided links to other web sites that result in the promotion of the Sands Series III Clinical Hyperbaric Chamber for intended uses that have not been

cleared by the agency. Two of these links include your affiliated clinic at Westside Hyperbarics (http://www.hyperbarics.net/westside) (same location as Sands), as well as your affiliated treatment/teaching facility, San Diego Hyperbarics, located at 446 26th Street, San Diego, California (http://www.hyperbarics.net/SanDiego).

The statements appearing on your links to Westside Hyperbarics and the San Diego Hyperbarics clinics imply that hyperbaric oxygen therapy (HBO Therapy) can be used to treat the following conditions which have not been cleared by the agency and would require the submission of a new 510(k): cerebral palsy; cerebral edema; closed head injuries; sickle cell anemia; near drowning; severed limbs; spinal cord injury; organic brain syndrome; stroke; Multiple Sclerosis; hearing loss; peripheral neuropathy; non-healing fractures; tendon and ligament injuries; delayed wound healing; decubitous ulcers, diabetic ulcers, venous stasis ulcers, and arterial insufficiency ulcers; frostbite; diabetic retinopathy; migraine and/or cluster headache; myocardial infarction; chronic fatigue; post-polio syndrome; Crohn's disease; Bell's palsy; Lyme disease; Menier's Disease; Reflex Sympathetic Dystrophy; poorly healing skin grafts; and brown recluse spider bites.

Additionally, the Westside Hyperbarics site contains the following claims implying treatment with hyperbaric oxygen therapy which have not been cleared by the agency: neovascularization; sporting injuries i.e., bruising and muscle damage; accelerate the healing from cosmetic surgery; spinal cord contusion; scleroderma; gastric ulcers; fibromyalgia; and HIV-related neuropathies.

Your web site also contains a list of intended uses distributed by the American College of Hyperbaric Medicine. In correspondence from Ms. Christy Foreman in July, 1998, a reviewer in FDA's Office of Device Evaluation (ODE), you were advised not to make any references to the intended uses identified by this organization (The American College of Hyperbaric Medicine) and to limit your intended uses to the 13 listed in paragraph 2 of this letter. Sands subsequently made a written commitment to the agency to limit its claims to these 13 intended uses.

We consider the claims on your web site and on your links to be major modifications in the intended use of the device. The regulations under 21 CFR 807.81(a)(3)(ii) state that when a manufacturer or distributor makes a major modification in the intended use of a device, he is required to submit a new 510(k) premarket notification to the agency prior to marketing the device with the additional claims.

Promoting the Sands Series III Clinical Hyperbaric Chamber for the above off-label claims causes your device to be adulterated within the meaning of section 501(f)(1)(B) of the Act in that it is a Class III device under section 513(f), and does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a), or an approved application for investigational device exemption (IDE) under section 520(g).

The Sands Series III Clinical Hyperbaric Chamber is also misbranded within the meaning of section 502(o) of the Act, in that a notice or other information respecting the modification in the intended use of the device was not provided to FDA as required by 21 CFR 807.81(a)(3)(ii), and the device was not found to be substantially equivalent to a predicate device.

This letter is not intended to be an all-inclusive list of deficiencies associated with your Sands Series III Clinical Hyperbaric Chamber. It is your responsibility to ensure adherence to each requirement of the Act and Federal regulations. The specific violations noted in this letter may represent practices used in other promotion or advertising materials, or verbal representations used by your firm. You are responsible for investigating and reviewing these materials or practices to assure compliance with applicable regulations. These limitations would also apply to the label of the product, user or instructional manuals, and any correspondence sent by Sands concerning the Sands Series III or the use of a hyperbaric chamber.

You should take prompt action to correct these violations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office, in writing, within 15 working days of receipt of this letter, outlining the specific steps you have taken to correct the cited violations. Your response should also include all steps being taken to address misleading information currently in the market place and actions to prevent similar violations in the future. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Steven E. Budabin, Consumer Safety Officer, Promotion and Advertising Policy Staff (HFZ-302), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's Los Angeles District Office. Please send a copy of your response to the District Director, Food and Drug Administration, (HFR-PA200), 19900 MacArthur Boulevard, Suite 300, Irvine, California 92612-2445.

Sincerely yours,

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health